REMARKS

Claims 5-7 and 38-40 are all the claims pending in the application; claims 5-7 and 38 are rejected; claims 39 and 40 are withdrawn[1].

Upon entry of the Amendment, claims 41-54 will be added and claims 5-7 and 38-54 will be pending.

As new claims 41-44 and 48-51 recite antibodies that bind to the polypeptide of SEQ ID NO:1 and pharmaceutical compositions comprising the antibodies, and as claims 5-7 and 38 recite the same subject matter, new claims 41-44 and 48-51 should be considered with claims 5-7 and 38 to be claims reciting the elected subject matter. Applicants understand that new claims 45 and 52-54 will likely be considered to be non-elected subject matter, in line with claims 39 and 40, and thus withdrawn.

Support for new claims 41-54 can be found in the specification as originally filed, for example, at page 9, lines 17 to 19; at page 10, lines 9-20; and in Figures 2A, 4B and 4D. In particular, support for the specific domains of SEQ ID NO:1 recited in the new claims may be found in Figure 2A.

No new matter has been added. Entry of the Amendment is respectfully requested.

I. Rejoinder

Upon allowance of claim 5, Applicants respectfully request rejoinder of claims 39-40 as both of these method claims depends from claim 5.

Similarly, upon entry and allowance of product claims 41-44 and 48-51, Applicants request rejoinder of method claims 45 and 52-54 as these claims depend from product claims 41-44 and 48-51.

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[1] While the Examiner indicates on the Office Action Summary sheet that claims 39 and 40 are "allowed", it is our understanding from the text of the Office Action (paragraph 1) that claims 39 and 40 are withdrawn. Applicants request clarification on this point by the Examiner.

II. Claim Rejections under 35 U.S.C. §103

At page 2 of the Office Action, claims 5-7 remain rejected, and claim 38 is newly rejected, under 35 U.S.C. §103(a) as being unpatentable over Purnelle et al. (Gen Bank accession number P25371) or Kirby et al. (Gen Bank accession number Q94960), further in view of Harlow et al. (Antibodies, A Laboratory Manual, Cold Spring Harbor Press, 1988, p. 142).

The Examiner maintains her position that the antibodies of Purnelle and Kirby would be expected to bind the polypeptide of SEQ ID NO:1 of the present application, and therefore recitation of an antibody that binds to SEQ ID NO:1 in the pending claims is *prima facie* obvious in view of the cited art.

Applicants respectfully traverse the Examiner's position for the reasons of record and the following additional reasons.

In particular, included in the instant Amendment are new claims 41-54. Claims 41-44 and 48-51 recite antibodies that bind particular domains of the polypeptide of SEQ ID NO:1. Thus, new claims 41-44 and 48-51 are drawn to antibodies that bind to specific portions of SEQ ID NO:1, addressing the Examiner's concern that "[n]othing in the claims requires that the antibodies bind to native protein" (page 7 of the Office Action). Neither Kirby nor Purnelle teaches antibodies that bind to the domains of the polypeptide of SEQ ID NO:1 as recited in the new claims.

Further, new claims 48-51 recite antibodies that bind to particular domains of the polypeptide of SEQ ID NO:1 and that permit intracellular accumulation of daunorubicin in MCF-7 cells that express the polypeptide of SEQ ID NO:1. Again, neither Kirby nor Purnelle teaches antibodies that have the recited activity.

Accordingly, Applicants respectfully assert that claims 5-7 and 38-40 are non-obvious in view of the arguments of record, and that new claims 41-54 are non-obvious as the combination of Kirby and Purnelle does not teach each and every limitation of new claims 41-54. Applicants therefore respectfully request reconsideration and withdrawal of this rejection.

III. Claim Rejections under 35 U.S.C. §112

At paragraph 6 of the Office Action, claim 38 is rejected under 35 U.S.C. §112, first paragraph, as being non-enabled.

Briefly, the Examiner notes that claim 38 recites a pharmaceutical composition comprising an isolated antibody that binds to SEQ ID NO:1. The Examiner goes on to state that inherent in the recitation of a pharmaceutical composition is the *in vivo* use thereof for the treatment of disease. The Examiner does not believe the specification to reasonably enable the skilled artisan in the use of the pharmaceutical composition in such treatment.

The Examiner further states that it appears that an object of the invention is to "provide a method of reversing the drug resistance of cancer cells by administering BCRP antibodies/a method of enhancing a patient's chemotherapy treatment for breast cancer by administering antibodies to the patient to inhibit BCRP. Thus it appears that the intended use of the claimed pharmaceutical composition is drawn only to the treatment of multidrug resistance cancers."

Applicants note that the standard for determining enablement of an invention in the U.S. is whether undue or unreasonable experimentation would be needed to practice an invention as claimed (*In re Wands*, 858 F.2d 731, 737, 8 USPQ 2d 1400, 1404 (Fed. Cir. 1988)). Stated another way, "the test for enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation." *United States v. Teletronics, Inc.*, 857 F.2d 778, 785 (Fed. Cir. 1988).

Applicants further note that as long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. §112 is satisfied. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Failure to disclose other methods by which the claimed invention may be made does not render a claim invalid under 35 U.S.C. §112. *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1533, 3 USPQ2d 1737, 1743 (Fed. Cir.), *cert. denied*, 484 U.S. 954 (1987).

Applicants respectfully note that in contrast to the Examiner's statement bridging pages 9-10 of the Office Action, an intended use for the pharmaceutical composition is not recited in claim 38.

Further, while the Examiner appears to argue that evidence of efficacy in treating patients is necessary to enable the invention as claimed, Applicants note that this is an improper requirement since patentability does not require establishment of clinical efficacy for a pharmaceutical composition. Applicants further note that enablement of the claims is not negatived by inclusion within their scope of potentially inoperative embodiments.

Applicants maintain, in the absence of a *reasonable basis* for questioning enablement, that the specification provides sufficient objective evidence to enable the invention as claimed, and that one of skill in the art would accept the assertion that the claimed pharmaceutical composition would be functional. For example, the present specification discloses that over-expression of BCRP is directly correlated with resistance to chemotherapeutic agents in human cells (see, e.g., page 3, lines 3-6; page 7, lines 8-10), a fact acknowledged by the Examiner (see page 8, lines 18-21). Further, the specification specifically states at page 10, lines 12-14, that "[m]onoclonal antibodies or fragments thereof can also be employed to assay for the presence or amount or [sic, "of"] BCRP in a particular biological sample."

One of skill in the art would readily understand that anti-BCRP antibodies could be used in *in vivo* diagnostic techniques, in addition to the other uses noted by the Examiner. For example, a radiolabeled antibody could be administered to the patient in order to locate and assessment BCRP levels in a particular tissue or region of the body.

Applicants also assert that the skilled artisan would accept that BCRP is a worthwhile target against which a pharmaceutical composition could be developed for use in the treatment of cancer. The generation of specific antibodies is now a routine procedure, and therefore no undue experimentation would be required to make the components of the claimed pharmaceutical compositions. Furthermore, since pharmaceutical formulation is also an extremely well developed science, the generation of the claimed pharmaceutical compositions would require nothing more than routine development work.

In light of these arguments, Applicants respectfully assert that claim 38 is fully enabled and request reconsideration and withdrawal of this rejection.

IV. Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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